Device for subcutaneous medication delivery using an offset flow path

Abstract

The present invention is an injection port assembly for subcutaneous delivery of medication. A multipart molded body has a soft cannula extending downward from a generally flat bottom surface and a self-sealing septum mounted at a top surface which is generally of a convex in shape sloping downward towards its outer perimeter. The body also has a tubular extension which is directed outward parallel to the skin's surface. A metal needle which penetrates through the septum off the center line of the infusion set and through the lumen of the soft cannula that is also not on the centerline of the infusion set is used for inserting the cannula through the skin. Once the soft cannula is placed subcutaneously, the needle is removed and an adhesive tape is placed over the single body and onto the skin beyond the body's outer perimeter. By having a distal section of the needle which is smaller in diameter as compared to most of the needle's length, and by having the soft cannula fit tightly onto the needle, most of the cannula's length will be in tension during insertion thereby preventing an accordion-like compressional failure of the cannula. A quick-release connector which is mounted on the centerline on the proximal end of the tubular extension or mounted directly on the injection port assembly allows the tubing connecting the injection port assembly to a portable medication pump to be disconnected when the patient showers or performs some similar activity. This mounting bias between the soft cannula and the connecting device also the manufacturing of the set to eliminate much of the close tolerance forming and needle grinding for the plastic and the connector.

What is claimed is:

1. An injection port for delivery of medication from an external source through a patient's skin comprising:

a generally flat, disk shaped main body formed from a from multiple molded elastomer including a septum formed integral at the center of the main body; and,

a cannula section formed from a single molded elastomer of a harder durometer as compared to the elastomer of the main body, the cannula section being joined with a pressure tight seal to the main body, the cannula section further having a flexible elongated cannula that protrudes in a generally downward direction from the main body.

Said cannula being located axially to the center of the infusion set and said flexible elongated cannula being mounted so as not centered to the main body of the infusion set.

Channels formed in the body so as to connect the offsetting cannulas.

2. The device of claim 1 wherein the septum that is formed integral with the main body has a slit to facilitate the passage of a plastic needle.

3. The device of claim 2 wherein guide ridges are situated around the septum to facilitate the placement of a plastic needle through the slit in the septum.

4. The device of claim 1 wherein the cannula section has two through holes each hole having an engagement means for engaging a releasable connector engagement means.

5. The device of claim 1 wherein both the upper and lower surfaces of the main body are generally of a concave shape.

6. The device of claim 1 wherein a pressure sensitive adhesive is applied to the bottom surface of the main body.

FIELD OF USE

This invention is in the field of injection ports for subcutaneous delivery of medication.

BACKGROUND OF THE INVENTION

Subcutaneous injection is a standard method for the delivery of medication. To facilitate frequent or continuous subcutaneous injection of medication, subcutaneous injection ports are often used. Such injection ports extend through the skin and may remain in place for several days. Currently a major application of such injection ports is to provide chronic delivery of medication such as insulin from portable pumps. When used with a pump, a fluid line is required to connect the injection port to the portable pump. Another application of a subcutaneous injection port is to permit multiple injections without the need to repuncture the skin. In this application, medication is injected from a standard hypodermic syringe and needle through a soft elastomer septum into the injection port which delivers the medication subcutaneously.

If a hollow metal needle is left in place through the skin to provide medication delivery, after one or two days the needle becomes uncomfortable to the patient. To solve this problem, a disposable injection port was described in U.S. Pat. No. 3,547,119 by Hall et al which has a soft, thin-walled cannula which is subcutaneously inserted over a metal needle. After insertion, the metal needle is removed leaving only the soft cannula through the skin. However the Hall invention has several limitations, namely:

(1) it is designed for infusion into the bladder and not for subcutaneous injection;

(2) the soft, thin-walled cannula which is subeutaneously inserted over the metal needle is placed in compression during insertion which can result in buckling of the cannula;

(3) the device has an extremely high profile making it impractical for ambulatory use where it is highly desirable to be hidden under clothing; and

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(4) it does not provide a bacterial filter.

More recently, a soft cannula subcutaneous injection set described in U.S. Pat. No. 4,755,173 by Kanopka et al has become available. While being lower in profile than the Hall device and specifically designed for subcutaneous delivery of medication, the Kanopka invention also has several shortcomings, namely:

(1) there is no method for disconnecting the tubing near the point of subcutaneous insertion, thus requiring a long length of tubing to remain connected while showering, exercising or performing other activities for which having a long length of tubing is disadvantageous;

(2) many separate parts are required to construct the injection set which increases costs and the probability of leakage;

(3) like the Hall device, the soft, thin-walled cannula which is subcutaneously inserted over a hollow needle is placed in compression during insertion which can result in buckling of the cannula;

(4) the multiple parts design results in a comparatively high outward protrusion from the skin;

(5) there is a fluid chamber within the device which is a dead space for medication; and

(6) the cylindrical segment of the catheter hub which extends below the holding pad presses on the skin and often becomes uncomfortable for the patient.

Another soft cannula subcutaneous injection port is described in U.S. Pat. No. 4,531,937 by Yates. The Yates device, however, has several disadvantages, namely:

(1) it requires a fluid trapping capability in the needle hub for the expulsion of air from the inside of the device;

(2) like the inventions by Hall and Kanopka, the soft, thin-walled cannula which is subcutaneously inserted over a hollow needle is placed in compression during insertion which can result in buckling of the cannula;

(3) it has a "stepped bore" diameter which forms a fluid chamber within the device which is a dead space for medication;

(4) it does not provide a bacterial filter; and

(5) it lacks a flat surface for attachment to the skin to prevent bending of the soft cannula during prolonged insertion.

Still another soft cannula injection port is described in U.S. Pat. No. 4,311,137 by Gerard.

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The Gerard device, however, has several disadvantages, namely:

(1) it requires a complex movable needle/septum assembly with one position for flushing and a second position for insertion;

(2) it has a lumen (referred to as a passage) which forms a fluid chamber within the device which is a dead space for medication;

(3) it does not provide a bacterial filter;

(4) the Gerard design results in a comparatively high outward protrusion from the skin; and

(5) like the inventions by Hall, Kanopka, and Yates, the soft, thin-walled cannula which is subcutaneously inserted over a hollow needle is placed in compression during insertion which can result in buckling of the cannula.

BRIEF SUMMARY OF THE PRESENT INVENTION

It is the goal of the present invention to overcome the several deficiencies of the prior art devices. Specifically, the present invention includes a quick-release connector which would typically be placed 5 to 10 cm from the device's main body. In another embodiment, the quick-release connector is placed directly onto the main body. Thus the soft cannula could remain in place through the skin while virtually all of the 100 plus cm of tubing connected to the portable pump could be temporarily detached and placed on a clean surface. When the main tubing is detached, a disposable sterilized cap can be placed over the quick-release connector to keep it sterile while showering, exercising or performing any other activity for which it is desirable to remove the long length of tubing. Furthermore, the connector can have a hard plastic needle which can penetrate through a previously slit septum on the injection port to provide a fluid path from an external portable pump, through the injection port and subcutaneously into the patient. The connector is centered to the body of the infusion port and the indwelling cannula is offset such that it is connected by a channel that prevents the connecting device from damaging the soft cannula when it is inserted and removed from the indwell housing.

Another feature of the present invention is that an in-line baeterial filter can be incorporated into the device so that when the tubing is removed, a cap is not needed to prevent bacteria from entering the injection port. Such an in-line bacterial filter will, when dry, allow venting of air from the device and when wet (after priming) prohibit air bubbles from passing into the body. This is of particular importance for intravenous use.

Another feature of the present invention is a soft elastomer septum for hypodermic needle injection of medication via the device. This septum may be directly incorporated into the main body of the injection port or it can be contained in a quick-release connector which mates with the quick-release connector on the injection port.

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Another feature of the present invention is to allow soft cannula angles between 20 and 80 degrees relative to the bottom surface of the device which could be advantageous for intravenous insertion.

Another novel feature of the present invention is that the needle guard which is removed prior to placing the needle and cannula through the skin can contain a broad spectrum antibiotic substance such as an antibiotic ointment. Thus, when the needle guard is removed, some ointment remains on the needle which ointment can decrease infections at the insertion site and also can act as a lubricant for the exterior surface of the cannula.

Still another feature of the cannula is that it can be made with a side port which can allow continued delivery of medication even if the end port becomes blocked. Also, the side port allows for more diffuse infusion of the medication so that it would be taken up more quickly into the body.

Still another feature of the present invention is a convex upper surface of the septum which allows the increase in sealing surface without substancially increasing the overall cylindrical width.

Still another object of this invention is to provide a quick-release fluid connector in close proximity to the main body or directly connected onto the main body.

Still another object of this invention is that the removable connector include a hard plastic needle that penetrates through the same septum that is used for the insertion needle assembly.

Still another object of this invention is that the main body has a flexible outer edge.

Still another object of this invention is that the soft, flexible cannula and the insertion needle cooperate to have most of the length of the soft, flexible cannula in tension when it is being subcutaneously inserted.

Still another object of this invention is that the needle hub be constructed of solid materials and not contain a fluid trapping means.

Still another object of this invention is to provide a fluid exit side port near the distal end of the soft cannula.

Still another object of this invention is that an antibiotic substance can be placed within the needle guard so that needle and soft cannula lubrication is provided and also because of the antibiotic substance the probability of infection at the infusion site is minimized.

Still another object of this invention to provide an essentially flat bottom surface without any protrusion which would press on the skin.

Still another object of this invention is to provide an in-line bacterial filter that can

prevent bacteria and/or air bubbles from passing into the patient.

Still another object of this invention is to allow connection through a flexible tube to a medication pump.

Still another object of this invention is to provide a soft elastomer septum for hypodermic injection of medication via the device.

Still another object of this invention is to separately mold a cannula section out of a comparatively hard plastic and insert it into a soft plastic main body whose great flexibility provides a more comfortable attachment to the skin.

These and other important objects and advantages of this invention will become apparent from the detailed description and drawings provided herein .

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a longitudinal cross section of the device shown in its form prior to insertion through the skin.

DETAILED DESCRIPTION OF THE DRAWINGS

In FIG. 1 is shown a cross-sectional view of the present invention as it would appear immediately prior to insertion through the skin. The medication injection port system 1 consists of four subassemblies, namely: the insertion needle assembly 5, the injection port assembly 10, the needle guard 30,and the quick-release connector assembly 40. The needle assembly 5 consists of a solid core needle 6 having a rigid plastic handle 9. The needle 6 could also be entirely or partially hollow and would typically be made from a stainless steel such as type 304. The diameter of the needle would typically be 0.45 mm except for the distal section 7 which would typically be 0.25 mm.

The injection port assembly 10 consists of a one piece main body 11 having a tubular body extension 12, an inlet lumen 13A, a tubular lumen 13B and a soft, flexible cannula 14 having a side port 15. Although it is ideal to have the body extension 12 and the soft cannula 14 molded into the main body 11, the present invention also envisions either one of these two parts to be formed separately and then bonded or adhesively joined into the main body 11. Within the two parts there are channels for connecting the fluid path so that fluid can move transversly and connect the soft cannula and the infusion needle. A removable needle guard 30 which is temporarily to the main body 11 protects the patient from being inadvertently stuck by the needle's sharp end prior to insertion through the skin. It is also envisioned that the adhesive could be placed on the bottom surface 20 of the body 11 where it would adhere to the skin after the needle guard is removed.

Within the needle guard 30 there can be placed an antibiotic ointment either at site 32B if it is desired that the ointment only cover the insertion puncture wound after insertion, or

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the ointment can be placed at position bottom of the body 11 if it is also desired to lubricate and coat the exterior surface of the cannula as it is inserted through the subcutaneous tissue. It should be noted that there is a closed, air tight volume within the needle guard 30 that would prevent drying out of an antibiotic ointment prior to the needle guard's removal from the bottom surface of the main body 11. It should also be noted that the shipping package which is used to sterilize and ship the injection port assembly could also have molded into it a needle guard section which could also include an antibiotic ointment.

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